REMARKS

1. In response to the Office Action mailed September 3, 2006, Applicants respectfully requests reconsideration. Claims 20, 22-25, 27, 29-34 and 36-38 were last presented for examination. In the outstanding Office Action, claims 20, 22-25, 27, 29-34, and 36-38 were rejected. By the foregoing Amendments, no claims have been amended, added or cancelled. Upon entry of this paper, claims 20, 22-25, 27, 29-34 and 36-38 will be pending in this application. Of these fifteen (15) claims, 3 claims (claims 20, 25 and 32) are independent.

2. Based upon the above Amendment and following Remarks, Applicants respectfully requests that all outstanding objections and rejections be reconsidered, and that they be withdrawn.

Art of Record

3. Applicants acknowledge receipt of form PTO-892 listing additional references identified by the Examiner.

Claim Rejections under 35 USC §103(a)

4. Claims 20, 22-25, 27, 29-34, and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,999,856 to Kennedy (hereinafter, "Kennedy") in view of U.S. Patent No. 5,758,651 to Nygard, *et al.* (hereinafter, "Nygard"). Applicants respectfully request that the Examiner reconsider and withdraw these rejections for at least the following reasons.

The Combination of Kennedy and Nygard is prima facie Improper

5. The proposed combination of Kennedy and Nygard is *prima facie* improper because the Examiner has failed to provide an appropriate basis for making the proposed combination. As stated by the Supreme Court in *KSR International Co. v. Teleflex Inc.*, "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently known in the prior art." (127 S.Ct. 1727, 1741 (2007).) The Supreme Court

recognized that "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some ***articulated reasoning with some rational underpinning to support the legal conclusion of obviousness***." (*See KSR*, 127 S.Ct. at 1741 (citing *In re Kahn*, 441 F.3d 977, 988 (C.A.Fed. 2006); emphasis added.) Applicants submit that the Examiner has completely failed to satisfy these legal obligations. The Examiner has done what has been viewed as circumspect by the Supreme Court and has only provided a conclusory and unsupported statement to justify the proposed combination of Kennedy and Nygard.

6. Kennedy describes a hearing assistance system having electric response audiometry functions for diagnostic, self-calibration, frequency-response parameter adjustment, feedback self-testing and automatic gain control purposes. (*See*, Kennedy, Abstract.) Kennedy describes an input transducer (*e.g.*, microphone) for receiving sound waves in the middle ear 35 region, and an output stimulator 215 which produces mechanical vibrations that are coupled to stapes 50 or other suitable auditory element in order to assist hearing. (*See*, Kennedy, col. 6, ll. 52-61.) A "response sensor" that is separate from stimulator 215 such as EEG device 300 or sensor 405 is described in Kennedy as being used to receive auditory response signals. Kennedy explains, "an auditory response signal, i.e. the portion of the received brain waves resulting from auditory neural pathway's response to the calibration stimuli, is extracted through electric response audiometry (ERA), such as through auditory brain-stem response (ABR), cortical electric response, electrocochleography, or other known audiometric techniques. In this embodiment, EEG device 300 is electrically coupled through external leads 305A-C to external electrodes 310A-C." (*See*, Kennedy, col. 7, ll. 21-32.) Kennedy then reiterates that its sensor leads are not the same as its transmission leads, as it states, "electrodes 310A-C typically comprise a ground electrode and two signal electrodes that are suitably placed ***for reception of the brain waves***." (*See*, Kennedy, col. 7, ll. 32-34; emphasis added.)

7. Nygard is directed to a system which enables telemetry from an auditory prosthesis in which an electrode array is used for both delivering electrical stimuli and for sensing evoked potentials between two electrodes on the array. (*See*, Nygard, Abstract.) As shown in FIG. 2 and described in Nygard, an external component 40 comprises various circuitry including digital processor 45, transmitter controller 46 and stage 43, RF link 41, receiver stage 42, and

comparator / timer controller 44. Nygard's internal component (implant) 10 comprises receiver coil 30, receiver stage 32, decoder 34, EAP amplifier / telemetry controller 35, switch 36, and transmitter stage 33. The electrodes and the electrode array of Nygard is not shown in FIG. 2. In Nygard, after "selected stimulus electrodes provide an electrical stimulus… a potential is detected across a selected sense pair of electrodes." (*See*, Nygard, col. 1, ll. 26-29.) Nygard states that the stimulus electrode pair and the sensing electrode pair may be the same electrodes, but are preferably different electrodes. (*See*, Nygard, col. 2, ll. 59-65.) The potential difference measured by the sensing pair is then "amplified by a suitable amplifier 20 to produce (ultimately) an EAP measurement on apparatus external to the patient. The amplified signal is sampled at 16 intervals and transmitted via the RF link." (*See*, Nygard, col. 2, ln. 66 – col. 3, ln. 1.) Nygard further states that the 16 samples are "averaged to further increase the signal to noise ration of the measurement." (*See*, Nygard, col. 4, ll. 14-16.)

8. In the Office Action, the Examiner relies upon Kennedy to teach "a high gain amplifier having a signal input and an electrode array configured to provide stimulation to the auditory nerve, and further configured to successively detect discrete values corresponding to an evoked neural response from the auditory nerve to said stimulation." (*See*, Office Action, pg. 2.) The Examiner relies upon Nygard to teach a "telemetry system with an electrode array 10 used both for delivering electrical stimuli and for sensing evoked potentials." (*See*, Office Action, pg. 3.) The Examiner then appears to be asserting that Nygard teaches stimulus pair 12 and 13 which senses the potential difference, and that this potential difference is amplified. (*See*, Office Action, pg. 3, "A stimulus pair 12 and 13 senses the difference is amplified by an amplifier 20.") The Examiner asserts that "it would have been obvious to one of ordinary skill in the art to implement the amplification of the difference between the sensed pair as disclosed by Nygard in order to calculate values to [represent] the neural response of the Kennedy reference." (*See*, Office Action, pg. 3.) Applicants assert that this conclusory statement provided by the Examiner clearly does not provide a rational underpinning to explain the proposed combination.

9. Kennedy teaches that "In one embodiment, input transducer 210 is an electromechanical transducer for receiving mechanical sound vibrations in the middle ear 35 region. In another embodiment, input transducer 210 is a microphone for receiving sound waves in the middle ear

35 region." (*See*, Kennedy, col. 6, ll. 49-53.) Furthermore, Kennedy teaches the measuring of "***brain waves resulting from*** [the] auditory neural pathway's response to the ***calibration stimuli***." (*See*, Kennedy, col. 7, ll. 24-25; emphasis added.) In other words, in Kennedy, the stimuli provided to the middle ear region causes activity in the brain, and Kennedy describes measuring that brain activity (and not, through sensors which measure such brain activity. Nygard on the other hand uses select electrodes to provide stimulation to and then directly measure the "evoked action potential" from the auditory nerve, and then amplifies the measured potential as described. (*See*, Nygard, col. 2, ll. 44-45.) Kennedy uses measurements of brain activity signals which are different in terms of the type, magnitude and other important factors from those measured directly from the auditory nerve. It is not clear, and the Examiner has failed to articulate a rationale or reasoning with some rational underpinning to support the Examiner's assertion that the amplifying the measured neural response can be adapted for use with the measuring of brain activity using such devices as EEG, among others as described in Kennedy. Furthermore, Applicants note that Kennedy appears to not need amplification of the brain activity measured as the activity measured apparently has sufficient magnitude such that amplification is not necessary. Again, the Examiner has failed to articulate an explanation as to why amplification of detected brain activity (e.g., using EEG) requires amplification.

10. Furthermore, the Examiner appears to be misinterpreting the actual teachings of Nygard, and then incorporating that misinterpretation into the examiner's suggested combination. In the Office Action, the Examiner states that in Nygard "a stimulus pair 12 and 13 senses the ***difference*** is amplified by an amplifier 20… It would have been obvious to one of ordinary skill in the art to implement the amplification of the ***difference*** between the sensed pair as disclosed by Nygard in order to calculate values to representing the neural response of the Kennedy reference." (See, Office Action, pgs. 3-4.) The Examiner appears to interpret Nygard as describing the taking of two separate measurements, first one measurement and then a second measurement, then determining the difference between those measurements, and then amplifying the determined difference. In fact, Nygard describes determining the potential differences at two electrodes as being a single measurement. Nygard describes, "a system for ***measuring*** the response of a neural system to stimulation by an auditory prosthesis, wherein selected ***stimulus electrodes provide an electrical stimulus***, and ***after a predetermined period*** a

potential is detected across a selected sense pair of electrodes." (*See*, Nygard, col. 1, ll. 24-29.) Nygard states, "the sense pair ***potential difference*** is amplified by a suitable amplifier 20 to produce (ultimately) an EAP measurement." (*See*, Nygard, col. 2, ln. 66 – col. 3, ln. 1.) Clearly, Nygard speaks only of amplifying the actual measurement (which is the potential difference between two sense electrodes) and not the difference between two separate measurements. This apparent misunderstanding is then used to draw an improper conclusion upon which this rejection is based.

11. The above cited case law makes it extremely clear that without a clear, articulated reason having some rational underpinning to explain the proposed combination, an obviousness rejection under 35 U.S.C. §103 cannot be maintained. (*See KSR.*, 127 S.Ct. at 1741.) As the "clear, articulated reason having some rational underpinning" must require a proper understanding and then any application of the references upon which the reasoning is based, which Applicants assert is not present with respect to at least Nygard, Applicants assert that the proposed combination of Kennedy with Nygard is *prima facie* improper and that the rejections under 35 U.S.C. §103 should be reconsidered and withdrawn.

The Proposed Combination Still Fails to Contain All Elements of Applicants' Claimed Invention

12. As set forth in §2142 of the M.P.E.P., "to establish a *prima facie* case of obviousness… the prior art reference (or references when combined) must teach or suggest all of the claim limitations." Applicants respectfully assert that even if the references were combined as proposed by the Examiner, the resulting combination would still fail to teach all elements of Applicants' claimed invention.

13. As explained in detail above, Nygard is directed to amplifying the measurement itself (which is the potential difference between two sense electrodes) and not the difference between two separate measurements. In contrast, Applicants' independent claim 20 recites, in part, a "wherein said first implantable subsystem is configured to ***set said reference voltage to a first*** of said ***detected discrete values at a first time and to a second*** of said detected ***discrete values at a second time***, wherein said ***amplifier is configured to amplify the difference between the first and second discrete values*** thereby obtaining a plurality of discrete values collectively

representing an unsaturated, high gain amplified version of the evoked neural response of the auditory nerve." (*See*, Applicants' claim 20, above; emphasis added.) Applicants assert that amplifying each of one or more measurements, as described in Nygard, does not teach the setting of a reference voltage to a first detected discrete value at a first time, and then to a second detected discrete value at a second time, and then amplifying the difference between those values at the first and second times, as recited by Applicants' independent claims.

14. Applicants further assert that Kennedy fails to teach that which is missing from Nygard. Therefore, for at least these reasons, Applicants assert that claim 20, and for similar reasons independent claims 25 and 32, are patentable over the combination of Kennedy and Nygard. Accordingly, Applicants respectfully request that the rejections of claims 20, 25 and 32under 35 U.S.C. §103 be reconsidered, and that it be withdrawn.

Dependent claims

15. The dependent claims incorporate all the subject matter of their respective independent claims and add additional subject matter which makes them independently patentable over the art of record. Accordingly, Applicants respectfully assert that the dependent claims are also allowable over the art of record.

Conclusion

16. In view of the foregoing, this application should be in condition for allowance. A notice to this effect is respectfully requested.

17. Applicants reserve the right to pursue any cancelled claims or other subject matter disclosed in this application in a continuation or divisional application. Any cancellations and amendments of above claims, therefore, are not to be construed as an admission regarding the patentability of any claims and Applicants reserve the right to purse such claims in a continuation or divisional application.

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